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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/514,312 | 02/28/2000 | Takahide Kasai | 31671-157328RK | 8281 |

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| EXAMINER |
|---|
| DI NOLA BARON, LILIANA |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/514,312 | KASAI ET AL. | |
| | Examiner | Art Unit | |
| | Liliana Di Nola-Baron | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *15-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

Receipt of Applicant's request for continued examination and amendment, filed on January 2, 2002, is acknowledged.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 15-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claims 15-39, the phrase "the coating agent has properties of a plastic fluid" renders the claims indefinite, because said properties are not defined in the claims and specification. Applicant's statement on page 14 of the specification, teaching that "the coating agents of the present invention are plastic fluids and have different physical properties than conventional types" is not accompanied by any definition of said physical properties, which render the invention different over said conventional types.

4. Regarding claims 15-39, the phrase "provides a pre-selected dissolution time" renders the claims indefinite, because it is not clear what is the length of the pre-selected dissolution time claimed according to the invention. The examples provided in the specification provide only the general teaching that the time at which dissolution begins can be controlled by the amount of coating, but the dissolution time encompassed by the invention is not disclosed.

5. Regarding claims 17-19 and 24-39, the phrase "a thickness effective to provide the pre-selected dissolution time" renders the claims indefinite, because a thickness range is not provided in the specification and in the claims.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 15-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Provonchee et al. in view of Jamas et al.

The claimed invention refers to a coating agent comprising enzyme-treated yeast cell wall fractions, a coated material comprising said coating agent and methods of controlling dissolution time of a coating, comprising applying said coating agent to a solid material.

Provonchee et al. discloses polysaccharide compositions of the gel-forming beta-1,3-glucan type and methods of preparing and using said polysaccharides (See e.g., col. 1, lines 6-14). Provonchee et al. teaches that the beta-1, 3-glucan polysaccharides of the invention are widely distributed in nature as components of yeast cell walls (See e.g., col. 1, lines 15-35). Provonchee et al. describes the Critical Temperature Neutralization (CTN) method for preparing solutions

and gels of the invention and teaches that the beta-1, 3-glucan polysaccharides are separated from a culturing method by known methods, heated and the pH of the solution is neutralized by addition of an acid (See e.g., col. 4, lines 4-66). Provonchee et al. teaches that the CTN method makes possible applications such as microencapsulation and formation of biodegradable therapeutic agent microcarriers (See e.g., col. 8, lines 53-68). Additionally, Provonchee et al. teaches that the gels of the invention may be used for controlled release of pharmaceuticals, preparation of food and coating of seeds, embryos, plantelets and the like (See e.g., col. 9, lines 1-39). Provonchee et al. teaches that appropriate selection of polysaccharide, thickness of the gel and concentration of the drug provides the coated pharmaceuticals with controlled release characteristics (See e.g., col. 9, lines 1-14).

Thus, Provonchee et al. provides controlled-release pharmaceuticals, by coating said pharmaceutical with acid-treated yeast cell wall components. Provonchee et al. is deficient in the fact that it does not include a plasticizer in the compositions of the invention.

Jamas et al. provides a composition and method utilizing yeast glucan as a dietary additive and explains that beta-glucans are the alkali-insoluble portion obtained from yeast cell walls (See e.g., col. 3, line 1 to col. 4, line 10). Jamas et al. teaches that the glucans can be treated with hydrolytic enzymes or an acid after extraction from yeast to decrease viscosity and increase water holding capacity (See e.g., col. 5, lines 11-62). Jamas et al. teaches that the dietary additive of the invention can be administered orally, the glucan can be administered alone or with other ingredients and the compositions of the invention can be in the form of tablet or powder and include additives, such as a plasticizer (See e.g., col. 6, line 66 to col. 7, line 20).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions disclosed by Provonchee et al., by adding a plasticizer and administer the composition in the form of tablet, as taught by Jamas et al. One of ordinary skill in the art would have been motivated to make such a modification to further control the release of the coated material. Because of the teachings of Jamas et al., that beta-glucan may be combined with a plasticizer, one of ordinary skill in the art would have a reasonable expectation that the coating agent claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Response to Arguments***

8. Applicant's arguments filed on January 2, 2002 have been fully considered but they have been found only partially persuasive.

9. Applicant's arguments regarding the 35 U.S.C. 102(b) rejection of claims 15, 17, 20, 22, 24 and 27 over Shank and the 35 U.S.C. 103 rejection of claims 15-37 over Shank in view of Jamas et al. of the previous Office action have been found persuasive. Accordingly, said rejections are withdrawn.

10. In response to Applicants argument, that the prior art (Provoncee et al.) discloses pseudo-plastic gels, it is noted that pseudo-plastic is still considered plastic and gels are fluid. The physical properties of the plastic fluids upon which Applicant relies are not defined in the claims and specification. Applicant's statement on page 14 of the specification, teaching that "the

coating agents of the present invention are plastic fluids and have different physical properties than conventional types" is not accompanied by any definition of said physical properties, which, according to Applicant, render the invention different over said conventional types.

11. In response to Applicants argument, that the prior art discloses coating agents with different solubility, pH dependency and oxygen permeability, it is noted that the limitations Applicants refer to are not in the claims. Furthermore, Applicants have not shown the criticality of said limitations for Applicants purpose.

12. In response to Applicants argument, that the prior art (Jamas et al.) discloses glucan as a dietary additive, it is noted that Applicant's claimed invention encompasses food products and food product materials.

13. In response to Applicants argument, that the prior art (Jamas et al.) does not suggest that glucan is a coating agent, it is noted that the prior art discloses glucan compositions comprising a coating material, such as a plasticizer, rendering obvious the combination of the two elements (See e.g., col. 7, line 20).

14. In response to Applicant's argument, that Jamas et al. does not teach or suggest dissolution control provided by coating, it is noted that Jamas et al. teaches that the compositions of the invention may include a coating material (See e.g., col. 7) and the purpose of the coating is to provide controlled release of a substance.

15. In response to Applicant's argument, that Jamas et al. teaches tablets, it is noted that Jamas et al. teaches that glucan can be administered alone, in a carrier or as a part of a complete nutritional food (See e.g., col. 7, lines 1-9).

16. In response to applicant's argument against the combination of the prior art, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

***Conclusion***

Claims 15-39 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

March 7, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600